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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**Pediatric Advisory Committee; Notice of Meeting**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee*: Pediatric Advisory Committee.

*General Function of the Committee*: To provide advice and recommendations to the agency on FDA's regulatory issues. The committee also advises and makes recommendations to the Secretary of Health and Human Services under 45 CFR 46.407 on research involving children as subjects that is conducted or supported by the Department of Health and Human Services, when that research is also regulated by FDA.

*Date and Time*: The meeting will be held on February 14, 2005, from 2 p.m. to 6 p.m. and on February 15, 2005, from 8 a.m. to 4:30 p.m.

*Location*: Center for Drug Evaluation and Research Advisory Committee Conference Room, rm. 1066, 5630 Fishers Lane, Rockville, MD.

*Contact Person*: Jan N. Johannessen, Office of Science and Health Coordination of the Office of the Commissioner (HF–33), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, rm. 14C–06) Rockville, MD 20857, 301–827–6687, e-mail: *jjohannessen@fda.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the



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Washington, DC area), code 8732310001. Please call the Information Line for up-to-date information on this meeting.

*Agenda*: On Monday, February 14, 2005, the committee will discuss an agency report on Adverse Event Reporting, as mandated in Section 17 of the Best Pharmaceuticals for Children Act (BPCA), for LOTENSIN (benazepril), BREVIBLOC (esmolol), MALARONE (atovaquone/proguanil), VIRACEPT (nelfinavir), XENICAL (orlistat), and GLUCOVANCE (glyburide/metformin). The committee will also be asked to advise the agency on how to improve the process and content of the adverse event reviews and reporting as mandated by BPCA.

On Tuesday, February 15, 2005, the committee will discuss risk evaluation, labeling, risk communication, and dissemination of information on potential cancer risk among pediatric patients treated for atopic dermatitis with topical dermatological immunosuppressants.

The background material will become available no later than the day before the meeting and will be posted under the Pediatric Advisory Committee (PAC) docket Web site at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm* (click on the year 2005 and scroll down to PAC meetings).

*Procedure*: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by February 7, 2005. Oral presentations from the public will be scheduled on Monday, February 14, 2005, between approximately 4 p.m. and 4:30 p.m. and on Tuesday, February 15, 2005, between approximately 12 noon and 12:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person by February 7, 2005, and submit

a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please notify Jan Johannessen at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: December 30, 2004

December 30, 2004.

William K Hubbard

William K. Hubbard,
Associate Commissioner for Policy and Planning.

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